UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 8, 2021

BioSig Technologies, Inc.

(Exact name of registrant as specified in its charter)

<u>001-38659</u>

(Commission File Number)

26-4333375 (IRS Employer Identification No.)

54 Wilton Road, 2nd Floor Westport, Connecticut

<u>Delaware</u> (State or other jurisdiction

of incorporation)

(Address of principal executive offices)

<u>06880</u> (Zip Code)

(203) 409-5444

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4 (c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of exchange on which registered |
|---|-------------------|--------------------------------------|
| Common Stock, par value \$0.001 per share | BSGM | The NASDAQ Capital Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company \Box

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On April 9, 2021, BioSig Technologies, Inc. (the "Company") issued a press release, attached hereto as Exhibit 99.1, announcing that that it had been invited by, and accepted, an invitation to join the Alliance for Artificial Intelligence in Healthcare (AAIH). The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by reference in such a filing. Furthermore, the furnishing of information under Item 7.01 of this Current Report on Form 8-K is not intended to constitute a determination by the Company that the information contained herein, including the exhibits hereto, is material or that the dissemination of such information is required by Regulation FD.

Item 8.01 Other Events

On April 8, 2021, the Company issued a press release announcing its Pure EPTM System was highlighted in a feature interview for the April issue of EP Lab Digest, a leading industry publication for the electrophysiology professionals. A copy of this press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| Exhibit Number | Description |
|----------------|---|
| 99.1 | Press Release, dated April 9, 2021 (furnished herewith pursuant to Item 7.01) |
| 99.2 | Press Release, dated April 8, 2021 |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL) |
| | |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: April 9, 2021

By: /s/ Kenneth L. Londoner Name: Kenneth L. Londoner Title: Executive Chairman



BioSig Invited to Join Alliance for Artificial Intelligence in Healthcare (AAIH)

• Global leaders, including Amazon, Bayer and GE Healthcare, joined the AAIH to date to collaborate on developing novel solutions to improve the quality of care and reduce failure rates

• The Company recently launched a new AI program with the Mayo Foundation for Medical Education

Westport, CT, April 09, 2021 -- BioSig Technologies, Inc. (NASDAQ: BSGM) ("BioSig" or the "Company"), a medical technology company commercializing an innovative signal processing platform designed to improve signal fidelity and uncover the full range of ECG and intra-cardiac signals, today announced that it had been invited by, and accepted, an invitation to join the Alliance for Artificial Intelligence in Healthcare (AAIH), following BioSig's major patent awards for its AI-based platform that the Company recently won from the U.S. Patent Office.

AAIH is the global advocacy organization for the advancement and use of artificial intelligence in healthcare to improve patients' lives and create more efficient, sustainable, and accessible healthcare systems. The AAIH and its member companies and organizations are dedicated to developing novel interventions and product solutions to reduce failure rates and costs while improving quality across the entire healthcare spectrum from biomedical discovery, clinical research, medical diagnostics and devices, and precision medicine. The initiative, which spans out of the Alliance for Regenerative Medicine, was formally launched in 2019 with 22 founders, including Amazon WS (NASDAQ: AMZN), Bayer (XETR: BAYN), GE Healthcare (NYSE: GE), GlaxoSmithKline (NYSE: GSK), and the University of Pittsburg.

"Artificial intelligence excels at analyzing and uncovering patterns in vast volumes of clinical data – a fundamental building block in improving patient care. BioSig is a company that is committed to providing superior technological solutions based on precise signal information. We believe that a joint effort between various healthcare community representatives is a much-needed step towards solving common challenges and accelerating the adoption of AI-powered solutions. We are excited to join the Alliance and collaborate with its members on our shared goals for improving the standards of patient care,' commented Kenneth L. Londoner, Chairman and CEO of BioSig Technologies, Inc.

BioSig recently launched a strategic collaboration with the Mayo Foundation for Medical Education and Research to develop a next-generation AI- and machine learningpowered software for the PURE EPTM System. The Company's platform technology provides signal information during the cardiac ablations for the treatments of arrhythmias or irregular heartbeats, a condition that affects over 33 million people worldwide¹. Under the terms of the newly launched AI initiative, the Company aims to develop novel technological solutions to improve existing therapies by combining the PURE EPTM's electrophysiological signals and other data sources.

The Company has also announced major strategic collaborations with other subject-matter experts to further the AI and machine learning applications of the PURE EPTM System in their collaboration for AI technical advisory services with Harvard- and MIT-trained computer scientist and physicist Dr. Wissner-Gross, of Reified. In 2020, the Company co-authored an abstract with Reified, titled 'Computational Reconstruction of Electrocardiogram Lead Placement,' that presented a new method for analyzing electrocardiograms that may ultimately help to improve the automated classification of patient conditions.

"This is an exciting time for artificial intelligence and machine learning applications in healthcare, and we look forward to contributing to next-generation technological solutions in the space," responded Dr. Wissner-Gross.

The global market for AI in healthcare is expected to grow from \$4.9 billion in 2020 to \$45.2 billion by 2026 at an estimated compound annual growth rate (CAGR) of 44.9%. According to Accenture, key clinical health AI applications, when combined, can potentially create \$150 billion in annual savings for the United States healthcare economy by 2026.

¹ Top 10 Things You should Know About Heart Rhythm; Scripps Health

About AAIH

The AAIH is a coalition of technology developers, pharmaceutical companies, and research organizations who have expressed the common goal of realizing the potential for AI and machine learning in healthcare to significantly improve quality of care, but who also recognize the need to address substantial industry challenges. By convening stakeholders to present a unified voice, we are working to establish responsible, ethical, and reasonable standards for the development and implementation of AI in healthcare. As an organization, the AAIH brings together industry, academia, research institutions, government NGOs, key opinion leaders, and other international stakeholders to develop appropriate regulatory principles. By engaging with a wide array of participants across the healthcare spectrum, the AAIH works to actualize the promise of artificial intelligence in medicine thereby improving patients' lives and creating more efficient, sustainable, and accessible healthcare systems. Learn more on www.theaaih.org.

About BioSig Technologies

BioSig Technologies is a medical technology company commercializing a proprietary biomedical signal processing platform designed to improve signal fidelity and uncover the full range of ECG and intra-cardiac signals (www.biosig.com).

The Company's first product, PURE EPTM System is a computerized system intended for acquiring, digitizing, amplifying, filtering, measuring and calculating, displaying, recording and storing of electrocardiographic and intracardiac signals for patients undergoing electrophysiology (EP) procedures in an EP laboratory.

Forward-looking Statements

This press release contains "forward-looking statements." Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward- looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) the geographic, social and economic impact of COVID-19 on our ability to conduct our business and raise capital in the future when needed, (ii) our inability to manufacture our products and product candidates on a commercial scale on our own, or in collaboration with third parties; (iii) difficulties in soluting financing on commercially reasonable terms; (iv) changes in the size and nature of our competition; (v) loss of one or more key executives or scientists; and (vi) difficulties in securing regulatory approval to market our products and product candidates. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's website at http://www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

Contact:

Andrew Ballou BioSig Technologies, Inc. Vice President, Investor Relations 54 Wilton Road, 2nd floor Westport, CT 06880 aballou@biosigtech.com 203-409-5444, x119



EP Lab Digest Features Physician Experience with the BioSig's Cardiac Signal Acquisition Technology

- Leading industry publication highlights the rising importance of intracardiac signals in complex cardiac ablations that treat irregular heart rhythm disorders
- · High-quality intracardiac signals are deemed essential to determine ablation endpoints

• PURE EPTM's signals are described as 'indispensable' by the physician user

WESTPORT, CT, April 08, 2021. BioSig Technologies, Inc. (Nasdaq: BSGM) ("BioSig" or the "Company"), a medical technology company commercializing an innovative signal processing platform designed to improve signal fidelity and uncover the full range of ECG and intra-cardiac signals, today announced the PURE EPTM System was highlighted in a feature interview for the April issue of EP Lab Digest, a leading industry publication for the electrophysiology professionals.

EP Lab Digest interviewed Deepak Gaba, MD, clinical electrophysiologist, and Shari Slyder, BS, RT, Managing Director of Cardiovascular Services, who currently use the PURE EPTM System at Memorial Hospital in South Bend, Indiana. The feature interview titled 'Improved Intracardiac Signal Visualization During RF and Cryo Procedures' highlighted the rising importance of intracardiac signals in complex ablations and the process of incorporating the PURE EPTM System into the practice at Memorial Hospital that conducts 480 EP cases annually.

According to Dr. Gaba and Mrs. Slyder, the ability to accurately discern local and far-field electrograms is essential for identifying arrhythmia substrate and guiding ablation endpoints. As the new high-density catheters and advanced electrode designs enter the market, there is a renewed focus on acquiring and displaying high-fidelity intracardiac signals. Dr. Gaba, who, along with his colleagues, has performed more than twenty-five procedures using PURE EPTM to date, describes the superior quality of PURE EPTM signals in different clinical scenarios using both Cryo and radiofrequency energy. Dr. Gaba further highlights that the signals acquired with the PURE EPTM System affect his decisions about arrhythmia's origination and optimal site of energy delivery. Additionally, Shari Slyder, a certified radiologic technician (AART), elaborates on the advantages of PURE EPTM's advanced noise shielding capabilities—a unique feature of its proprietary architecture. Read the full article here.

"As we continue expanding our clinical footprint, we are rapidly learning how the cardiac information provided by PURE EP TM complements other technologies and elevates the experience in the electrophysiology lab. The growing physician acceptance of our technology is a result of our dedication to addressing unmet clinical needs. We are pleased to see the increased industry's focus on the importance of high-fidelity intracardiac signals across all types of cardiac arrhythmias," commented Olivier Chaudoir, Senior Director of Marketing at BioSig Technologies, Inc.

The PURE EPTM System is being used in all types of arrhythmia cases, including atrial fibrillation, ventricular tachycardia, and atrial flutter. More than 680 patient cases have been conducted with the technology to date. The Company continues to accumulate significant amounts of data to be utilized in the new product development to complement the PURE EPTM System, including AI- and machine learning-powered applications and modules for electrophysiology.

The article is the latest interview in a series of publications featuring BioSig's PURE EPTM System in industry-leading media outlets. Previous publications include a January 2021 editorial by EP Lab Digest's Editor-in-Chief, Bradley P. Knight, M.D., FACC, FHRS, a December 2020 feature interview with Rafaelle Corbisiero, M.D. and Pedram Kazemian, M.D. of Deborah Heart and Lung Center, and an April 2020 interview with Andrea Natale, M.D. of Texas Cardiac Arrhythmia Institute at St. David's Medical Center.

About BioSig Technologies

BioSig Technologies is a medical technology company commercializing a proprietary biomedical signal processing platform designed to improve signal fidelity and uncover the full range of ECG and intra-cardiac signals (www.biosig.com).

The Company's first product, PURE EPTM System, is a computerized system intended for acquiring, digitizing, amplifying, filtering, measuring and calculating, displaying, recording and storing of electrocardiographic and intracardiac signals for patients undergoing electrophysiology (EP) procedures in an EP laboratory.

Forward-looking Statements

This press release contains "forward-looking statements." Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "amis," "believes," "hopes," "potential" or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) the geographic, social and economic impact of COVID-19 on our ability to conduct our business and raise capital in the future when needed, (ii) our inability to manufacture our products and product candidates on a commercial scale on our own, or in collaboration with third parties; (iii) difficulties in obtaining financing on commercially reasonable terms; (iv) changes in the size and nature of our competition; (v) loss of one or more key executives or scientists; and (vi) difficulties in securing regulatory approval to market our products and product candidates. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's website at http://www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

Contact:

Andrew Ballou BioSig Technologies, Inc. Vice President, Investor Relations 54 Wilton Road, 2nd floor Westport, CT 06880 aballou@biosigtech.com 203-409-5444, x133